- 1 GENERAL GOVERNMENT CABINET
- 2 Board of Dentistry
- 3 (AMENDMENT REGULATION)
- 4 201 KAR 8:541. Dental practices and Prescription Writing.
- 5 RELATES TO: KRS 313.060, 313.085, 422.317, 42 U.S.C. 300ee-2 note, <u>2012 KY Acts Ch. 1</u>
- 6 STATUTORY AUTHORITY: KRS 313.060(1), 2012 KY Acts Ch. 1
- 7 NECESSITY, FUNCTION, AND CONFORMITY: 42 U.S.C. 300ee-2 note requires each state to
- 8 institute the guidelines issued by the United States Centers for Disease Control and Prevention or
- 9 guidelines that are equivalent to those promulgated by the Centers for Disease Control and Prevention
- 10 concerning recommendations for preventing the transmission of the human immunodeficiency virus and
- the hepatitis B virus during exposure-prone invasive procedures, and KRS 313.060(1) requires the board
- 12 to promulgate administrative regulations relating to dental practices that shall include minimal
- 13 requirements for documentation and Centers for Disease Control compliance. This administrative
- regulation establishes requirements for preventing the transmission of the human immunodeficiency
- virus and the hepatitis B virus during exposure-prone invasive procedures and includes minimal
- 16 requirements for documentation and Centers for Disease Control compliance.
- 17 Section 1. Definitions.
- 18 (1) "Invasive procedure" means a procedure that penetrates hard or soft tissue.

- 1 (2)"Oral Surgery" means any manipulation or cutting of hard or soft tissues of the oral or maxillofacial
- 2 <u>area and associated procedures, by any means, as defined by the American Dental Association, utilized</u>
- 3 by a dentist licensed by this chapter and within their scope of training and practice.
- 4 Section 2. Minimum Documentation Standards for all Dental Patients. (1) Each patient's dental records
- 5 shall be kept by the dentist for a minimum of:
- 6 (a) Seven (7) years from the date of the patient's last treatment;
- 7 (b) Seven (7) years after the patient's eighteenth (18) birthday, if the patient was seen as a minor; or
- 8 (c) Two (2) years following the patient's death.
- 9 (2) Each dentist shall comply with KRS 422.317 regarding the release of patient records.
- 10 (3) The dentist shall keep accurate, readily accessible, and complete records which include:
- 11 [Each patient record for a dental patient in the Commonwealth of Kentucky shall include at a
- 12 minimum:
- 13 (a) The patient's name;
- 14 (b) The patient's date of birth;
- 15 (c) The patient's medical history and documentation of the physical exam of the oral and perioral
- 16 tissues;
- 17 (d) The date of treatment;
- 18 (e) The tooth number, surfaces, or areas to be treated;
- 19 (f) The material used in treatment;
- 20 (g) Local or general anesthetic used, the type, and the amount;
- 21 (h) Sleep or sedation dentistry medications used, the type, and the amount; and
- 22 (i) Diagnostic, therapeutic, and laboratory results if any;
- 23 (j) The findings and recommendations of and evaluations and consultations if any;

- 1 (k) Treatment objectives;
- 2 (1) All medications, including date, type, dosage, and quantity prescribed or dispensed; and
- 3 (m) Any post treatment instructions;
- 4 [A complete list of prescriptions provided to the patient, the amount given, and the number of refills
- 5 indicated.]
- 6 Section 3. Prescription writing privileges. (1) Pursuant to KRS 313.035 a dentist licensed under this
- 7 chapter may prescribe any drug necessary within the scope of their practice with the following
- 8 <u>conditions, provided the dentist :</u>
- 9 (a) is licensed pursuant to 201 KAR 8:532;
- 10 (b) has obtained a license from the Drug Enforcement Administration;
- 11 (c) <u>has enrolled with and utilizes the Kentucky All-Scheduled Prescription Electronic Reporting</u>
- 12 System as required by 2012 KY ACTS CH. 1 and Section 2(4) (b) of this regulation;
- 2) A dentist may not compound any scheduled drugs or dispense any Schedule I, Schedule II, or
- Schedule III controlled substances containing hydrocodone for use by the patient outside the
- office setting.
- 16 Section 4. Prescribing of Controlled Substances by Dentist
- 17 (1) Prior to the initial prescribing of any controlled each dentist shall:
- 18 (a) Obtain and review a KASPER report for all available data on the patient, document relevant
- information in the patient's record and consider the available information to determine whether it is
- 20 medically appropriate and safe to prescribe a controlled substances. This requirement to obtain and
- 21 review a KASPER report shall not apply to:

- 1 (1). a dentist who prescribes a Schedule III or one of the Schedule IV controlled substances listed in
- 2 subsection two (2) of this section after the performance of oral surgery provided no more than a 72 hour
- 3 <u>supply of such controlled substance is prescribed;</u>
- 4 (2). a dentist prescribing or dispensing Schedule IV or V controlled substances other than those listed in
- 5 this specific subsection. The dentist shall obtain and review a KASPER report before initially
- 6 prescribing any of the following Schedule IV controlled substances:
- 7 (a) Ambien;
- 8 <u>(b) Anorexics;</u>
- 9 (c) Ativan;
- 10 (d) Klonopin
- 11 (e) Librium
- 12 (f) Nubain
- 13 (g) Oxazepam
- 14 (h) Phentermine
- 15 <u>(i) Soma</u>
- 16 <u>(j) Stadol</u>
- 17 <u>(k) Stadol NS</u>
- 18 (l) Tramadol
- 19 (n) Versed, and,
- 20 (o) Xanax; or,
- 21 (3) pre-appointment medication for the treatment of procedure anxiety provided the prescription is
- 22 limited to a two day supply and has no refills.

- 1 (b) Obtain a complete medical history and conduct a physical examination of the oral or maxillofacial
- 2 <u>area of the patient and document the information in the patient's medical record;</u>
- 3 (c) Make a written treatment plan stating the objectives of the treatment and further diagnostic
- 4 <u>examinations required;</u>
- 5 (d)Discuss the risks and benefits of the use of controlled substances with the patient, the patient's parent
- 6 if the patient is an unemancipated minor child, or the patient's legal guardian or health care surrogate,
- 7 <u>including the risk of tolerance and drug dependence;</u>
- 8 (e)Obtain written consent for the treatment.
- 9 (2) A dentist may provide one (1) refill within 30 (thirty) days of the initial prescription for the same
- 10 controlled substance for the same amount or less or prescribe a lower Schedule drug for the same
- amount without a clinical reevaluation of the patient by the dentist.
- 12 (3) A patient who requires additional prescriptions for a controlled substance shall be clinically
- reevaluated by the dentist and the all provisions of this section followed.
- Section 5. Penalties and Investigations (1) Pursuant to the provisions in 2012 KY ACTS CH. 1 and the
- procedures set forth in KRS chapter 313, a licensee convicted of a felony offense related to prescribing
- and dispensing of a controlled substance shall, at a minimum, have a life-time revocation of any and all
- scheduled drug prescribing privileges.
- 18 (2) Pursuant to the provisions in 2012 KY ACTS CH. 1 and the procedures set forth in KRS chapter
- 19 313, a licensee convicted of a misdemeanor offense relating to the prescribing of a controlled shall, at a
- 20 minimum, have a 5 year revocation of any and all scheduled drug prescribing privileges.
- 21 (3) Pursuant to the provisions in 2012 KY ACTS CH. 1 and the procedures set forth in KRS chapter
- 22 313, a licensee disciplined by a licensing board of another state relating to the improper, inappropriate,
- or illegal prescribing or dispensing of controlled substances shall, at a minimum, have the same

- disciplinary action imposed by this state or the disciplinary action prescribed in (1) or (2) whichever is
- 2 greater.
- 3 (4) Pursuant to the provisions in 2012 KY ACTS CH. 1 and the procedures set forth in KRS chapter
- 4 313, a licensee who is disciplined in another state or territory who holds a Kentucky license and fails to
- 5 notify the Board in writing of the disciplinary action within 30 days of the finalization of the action shall
- 6 be subject to not less than a \$1000.00 fine.
- 7 (5) Pursuant to the provisions in 2012 KY ACTS CH. 1 and the procedures set forth in KRS chapter
- 8 313, a licensee who fails to register for an account with the Kentucky All Scheduled Prescription
- 9 Electronic Reporting System or who fails to meet the requirements of Section 4 of this regulation shall
- receive a private admonishment from the board and be given no more than thirty (30) days to become
- compliant after which time the dentist shall be subject to no less than a \$500.00 fine.
- 12 (6) The Law Enforcement Committee of the Board shall produce a charging decision on the complaint
- within one hundred twenty (120) days of the receipt of the complaint, unless an extension for a definite
- period of time is requested by a law enforcement agency due to an ongoing criminal investigation.
- 15 Section [3]. 6. Infection Control Compliance. (1) Each licensed dentist in the Commonwealth of
- 16 Kentucky shall:
- 17 (a) Adhere to the standard [universal] precautions outlined in the Guidelines for Infection Control in
- Dental Health-Care Settings published by the Centers for Disease Control and Prevention; and
- 19 (b) Ensure that any person under the direction, control, supervision, or employment of a licensee whose
- 20 activities involve contact with patients, teeth, blood, body fluids, saliva, instruments, equipment,
- 21 appliances, or intra-oral devices adheres with those same standard [universal] precautions.
- 22 (2) The board or its designee shall perform an infection control inspection of a dental practice utilizing
- 23 the Infection Control Inspection Checklist.

- 1 (3) Any dentist who is found deficient upon an initial infection control inspection shall have thirty (30)
- 2 days to be in compliance with the guidelines and submit a written plan of correction to the board. The
- dentist may receive a second inspection after the thirty (30) days have passed. If the dentist fails the
- 4 second inspection he or she shall be immediately temporarily suspended pursuant to KRS 313.085 until
- 5 proof of compliance is provided to the board and he or she shall pay the fine as prescribed in 201 KAR
- 6 8:520.
- 7 (4) Any licensed dentist, licensed dental hygienist, registered dental assistant, or dental assistant in
- 8 training for registration who performs invasive procedures may seek counsel from the board if he or she
- 9 tests seropositive for the human immunodeficiency virus or the hepatitis B virus.
- 10 (5) Upon the request of a licensee or registrant, the executive director of the board or designee shall
- convene a confidential expert review panel to offer counsel regarding under what circumstances, if any,
- the individual may continue to perform invasive procedures.
- Section [4.] 7. Termination of a Patient-Doctor Relationship. In order for a licensed dentist to terminate
- the patient-doctor relationship, the dentist shall:
- 15 (1) Provide written notice to the patient of the termination;
- 16 (2) Provide emergency treatment for the patient for thirty (30) days from the date of termination; and
- 17 (3) Retain a copy of the letter of termination in the patient records.
- Section [5]. 8. Incorporated by Reference. (1) The following material is incorporated by reference:
- 19 (a) "Guidelines for Infection Control in Dental Health-Care Settings", December 2003; and
- 20 (b) "Infection Control Inspection Checklist", July 2010.
- 21 (2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the
- 22 Kentucky Board of Dentistry, 312 Whittington Parkway, Suite 101, Louisville, Kentucky 40222,

- 1 Monday through Friday, 8 a.m. through 4:30 p.m. This material is also available on the board's Web site
- 2 at http://dentistry.ky.gov. (37 Ky.R. 624, Am. 1629; eff. 2-4-2011.)

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	July 24, 2012
DR. ADAM K RICH DMD, Board President	Date

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held on Tuesday, September 25, 2012, at 9:00 a.m. at the office of the Board of Dentistry, 312 Whittington Parkway, Suite 101, Louisville, KY 40222. Individuals interested in being heard at this hearing shall notify this agency in writing no later than September 24, 2012, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made.

If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted until September 25, 2012.

Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

Contact person: Brian K. Bishop, Executive Director, Board of Dentistry, 312 Whittington Parkway, Suite 101, Louisville, KY, 40222. Phone (502) 429-7280, fax (502) 429-7282, email briank.bishop@ky.gov.

## REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation #:	201 KAR 8:541. Dental practices and Prescription Writing.
Contact Person:	Brian K. Bishop, Executive Director
	Board of Dentistry
(1) Provide a brief summary of:	
requirements and procedures dentist as re	oes: This administrative regulation establishes elated to documentation of patient records, the writing of ection control, and termination of the doctor patient 2012 KY Acts Ch. 1.
implement KRS 313 and 2012 KY Acts Cladministrative regulations regarding the	egulation: This administrative regulation is necessary to h. 1, which requires the board to promulgate requirements for documentation in a patient record, the ations, infection control, and other parts of the dental
administrative regulation is necessary to i requires the board to promulgate adminis	onforms to the content of the authorizing statute: This mplement KRS 313 and 2012 KY Acts Ch. 1, which strative regulations regarding the requirements for riting of prescriptions, penalties for violations, infection etice.
of the statutes: This administrative regulat Acts Ch. 1, which requires the board to pr	ion is necessary to implement KRS 313 and 2012 KY romulgate administrative regulations regarding the ent record, infection control, and other parts of the

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:
(a) How the amendment will change this existing administrative regulation: This amendment will bring the board and the profession into compliance with the requirements of 2012 KY Acts Ch. 1
(b) The necessity of the amendment to this administrative regulation: 2012 KY Acts Ch. 1 requires the Board to implements this amendment no later than September 2012.
(c) How the amendment conforms to the content of the authorizing statute: This amendment meets all the requirements of 2012 KY Acts Ch. 1
(d) How the amendment will assist in the effective administration of the statutes: This amendment will implement the provisions of 2012 KY Acts Ch. 1 related to the writing of prescriptions by dentist licensed in the Commonwealth.
(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation will affect the 3119 dentist currently licensed by the board as well as any new dentist licensed by the board in the future. Additionally, the Kentucky Board of Dentistry will be affected by this administrative regulation.
(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:
(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: <b>This new regulation will require all licensees to register with KASPER.</b>

- (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There may be licensees who do not own a computer system in their office will with this regulation they will have to purchase a computer system to access KASPER.
- (c) As a result of compliance, what benefits will accrue to the entities identified in question (3): The Kentucky Board of Dentistry is the regulatory agency and accrues no benefits from the regulations but rather provides enforcement of the chapter and processes for it licensees to legally practice dentistry in the Commonwealth.
- (5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation: The Board is a self-funded agency whose budget was approved in HB 1 of the 2010 Extraordinary Session of the General Assembly. HB 1 provided for FY 2010 2011 an allotment of \$705,400 and for FY 2011 2012 and allotment of \$714,000. The Kentucky Board of Dentistry receives no monies from the General Fund.
  - (a) Initially: No additional costs are expected.
  - (b) On a continuing basis: No additional costs are expected.
- (6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The implementation and enforcement of this regulation are fully funded by licensing fees paid by dentists as part of compliance with this regulation.
- (7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: **The fees found in 201 KAR 8:520 make the agency financially solvent.**

- (8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation does not establish fees or directly or indirectly increase any fees.
- (9) TIERING: Is tiering applied? Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all licensed dentist.

## FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No. 201 KAR 8:541. Contact Person: Brian K. Bishop, Executive Director, **Board of Dentistry** 1. Does this administrative regulation relate to any program, service, or requirements of a state or local government (including cities, counties, fire departments, or school districts)? Yes <u>X</u> No \_\_\_\_ If yes, complete questions 2-4. 2. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Board of Dentistry is the only state government entity which will be impacted by this regulation. 3. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 313 and 2012 KY Acts Ch. 1 4. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. There will be no new net fiscal effect on the Kentucky Board of Dentistry as the agency is a fully selffunded agency and receives no general fund dollars.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year?

Compliance with this regulation will provide the agency with enough money to meets its budgetary obligations as set forth in 2012 KY ACTS CH. 1 of the 2012 Extraordinary Session of the General Assembly.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years?

Compliance with this regulation will provide the agency with enough money to meets its budgetary obligations as set forth in 2012 KY ACTS CH. 1 of the 2012 Extraordinary Session of the General Assembly.

(c) How much will it cost to administer this program for the first year?

FY 2010 – 2011 as allocated in HB 1 from the 2012 Extraordinary Session of the General Assembly is \$705,400

(d) How much will it cost to administer this program for subsequent years?

FY 2011 – 2012 as allocated in HB 1 from the 2012 Extraordinary Session of the General Assembly is \$714,000

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

## SUMMARY OF MATERIAL INCORPORATED BY REFERENCE

- (1) The "Guidelines for Infection Control in Dental Health-Care Settings" is the 76 page newsletter published by the Center for Disease Control (CDC) that outlines the universal precautions all dental health-care providers are required to follow. KRS 313 and 2012 KY Acts Ch. 1 requires the board to define procedures and requirements for compliance with CDC guidelines.
- (2) The "Infection Control Inspection Checklist" is the 2 page form used during inspections of dental practices to verify that the practice is in compliance with CDC guidelines. KRS 313 and 2012 KY Acts Ch. 1 requires the board to define procedures and requirements for compliance with CDC guidelines.